MAY 17 2006

510(k) Summary
(Revised)
510(k) K060412

Submitted By:

ASDM Pty Ltd
2/12 Frederick Street
St Leonards, NSW 2065
Australia
Tel: +61 2 9439 4448
Fax: +61 2 9439 4441

Date: 1 May 2006

Submitted By : Graham J Blucher, Quality and Regulatory Affairs Manager.

Trade Name: Active Unicompartmental Knee System

Classification Name: Prosthesis, knee joint, femorotibial, polymer/metal semi constrained cemented prosthesis – HRY

Common/Usual Name: Knee prosthesis, Unicompartmental.

Substantial Equivalence:

The Active Unicompartmental Knee is substantially equivalent to the Repicci II Unicondylar Knee, K971938.

Product Description:

Device

The Active Unicompartmental Knee System is a modular re-surfacing uni-compartmental knee implant system, consisting of a metallic femoral component and a UHMWPE partial tibial component.

Femoral Component

The femoral component is an anatomic, asymmetrically designed prosthesis manufactured from cast cobalt/chrome/molybdenum alloy conforming to ASTM F75. The prosthesis was designed for optimal weight transmission and flexion, while providing maximum contact area to reduce material stress on the tibial component. The design incorporates a rotation of the condyle from flexion to extension aspects. From the medial lateral view, the condylar geometry has a radial inward and upward sweep in the coronal plane, which assists in maximizing the contact area. The design incorporates a central web, and two stabilizing pegs. It is available in five sizes, in both anatomical aspects.

Tibial Component

The tibial component is an asymmetrical component manufactured from Ultra High Molecular Weight Polyethylene that meets the requirements of ASTM F468. The components have a hemispherical surface, with a mild curvature. They incorporate a PMMA fixation groove around the periphery of the component, and a waffle pad base, and an angled stabilizing peg on the anterior half of the inferior surface. The tibial components are available in six sizes for each anatomical aspect, with three thickness available in each size.

Intended Use/Indications for Use

The Active Unicompartmental Knee System is a modular unicompartmental system that is intended to resurface one diseased or damaged condyle of a knee where the other condyle remains intact. It is intended to be used only with bone cement in patients suffering from the following conditions:

- **Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.**
- **Inflammatory degenerative joint disease, excluding rheumatoid arthritis.**
- **Correction of functional deformity such as varus or valgus deformities.**

Testing

The components of the Active Unicompartmental Knee System were tested by means of FEA mechanical testing, microstructural evaluation and visual and metrological examination. Testing consisted of a range of stress testing on both femoral and tibial components by means of FEA, fatigue testing of the femoral component, adhesion testing of the tibial component, and microstructure analysis of the femoral component. Further testing was conducted on the influence of heat treatment on the CoCrMo components, and the effect of varying the web height.

When compared to other unicompartmental knee designs, the Active Unicompartmental knee system demonstrated similar performance characteristics.

Bio-compatability

The Active Unicompartmental Knee is manufactured from materials designed and used for surgical implant applications. The materials used are Chrome Cobalt Molybdenum alloy meeting the requirements of ASTM F75, and Ultra High Molecular Weight Polyethylene meeting the requirements of ASTM F648.

Additionally a risk analysis, and an associated independent report on the effects of the manufacturing process on these materials, has indicated that the process is unlikely to impact on the safety of the materials used.

Sterilization

The metal components are sterilized by exposure to 25 to 42 kGy (2.5 to 4.2 Mrad) gamma radiation, as per the requirememnts of ISO 11137.

The Polyethylene components are sterilized by exposure to Ethylene Oxide, as per the requirements of EN 550.

Conclusion

The performance testing has demonstrated that the Active Unicompartmental Knee System is substantially equivalent to the Repicci II Unicondylar Knee, K971938, and other similar marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Australian Surgical Design and Manufacture
c/o Mr. James F. Logan
Director General
Medical Reports Exchange, Inc.
2530 Riva Road, Suite 308
Annapolis, Maryland 21401

Re: K060412
Trade/Device Name: Active Unicompartmental Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: May 02, 2006
Received: May 09, 2006

Dear Mr. Logan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

(Revised)

510(k) Number (if known): _K060412

Device Name: _____Active Unicompartmental Knee System

Indications for Use:

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- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease excluding rheumatoid arthritis
- Correction of functional deformity such as varus or valgus deformities.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060412